EXHIBIT D

Plaintiffs' Responses to Defendants' Invalidity Contentions (excerpted and highlighted)

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH, Plaintiffs, v. NATCO PHARMA LIMITED and NATCO PHARMA INC., Defendants.	Honorable Robert Kirsch, U.S.D.J. Civil Action No. 23-796 (RK) (TJB) (Consolidated) [redacted]

PLAINTIFFS' RESPONSES TO DEFENDANTS'
INVALIDITY CONTENTIONS ('562 PATENT)

[redacted]

which is not limited to the selection of PARP-1 inhibitors specifically in response to the identification of HR deficient cancer cells in the claimed patients." Contentions at 230. As an initial matter, Defendants are incorrect to the extent they suggest that PARP-1 inhibitors were a proven cancer therapy at the priority date. To the contrary, while researchers had speculated about the possibility of developing a cancer treatment using a PARP-1 inhibitor, all of those attempts before the priority date had failed. Only after the disclosure of the invention in the '562 patent and its priority application were any PARP-1 inhibitors successful in clinical trials or approved for the treatment of human patients. At the priority date, the POSA would not have had a reasonable expectation of success in using PARP-1 inhibitors to treat any human patient, let alone in the context of the specific claimed method.

But Defendants are also incorrect to the extent they suggest that the general use of PARP-1 inhibitors outside of the context of the other features of the claim renders the claim obvious. The asserted claim is a combination of specific steps that must all be performed to practice the method. Defendants' bare assertion without citation that the use of PARP inhibitors generally would motivate the POSA to administer PARP-1 inhibitors to treat HR deficient tumor cells in a patient with a familial predisposition to gene-linked hereditary cancer falls far short of meeting Defendants' burden of clear and convincing evidence of obviousness.

Defendants also contend that the asserted claim is not limited to administering PARP-1 inhibitors as a monotherapy. Contentions at 232. Even assuming that Defendants are correct, Defendants do not even attempt to argue that it would have been obvious to administer PARP-1 inhibitors and another cancer therapy in combination with the other steps of the asserted claim. As discussed above, Defendants must prove that it would have been obvious to perform all of the steps of the asserted claim in combination, and they do not even attempt to do so.

[redacted]

Dated: May 24, 2024

Respectfully submitted,

/s/ Charles H. Chevalier
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